PLEASE USE THE FOLLOWING TABLE TO COMPLETE THE HUMAN SUBJECTS SECTION.

This section is due in the Research Office April 15 or October 15.

Human Studies Section (no limit, be succinct - not included in 25-page limit for narrative). If form 10-1313-1, Block 19, Human Subjects is checked "Yes," create a section heading titled "Human Subjects." Applicants must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan. In this section, provide information to **address all four evaluation criteria below** as they apply to the research proposed. **Applications that fail to comply will be withdrawn without review.**

Leave questions intact and fill in your response in the block below. The answer section of the table will expand. This section can then be inserted into the application.

(1.) Risk to Subjects

(a) *Human Subjects Involvement and Characteristics*: Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

(Fill in answer to above question)

(b) *Sources of Materials*: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(Fill in answer to above question)

(c) *Potential Risks*: Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate the therapeutic risk from research risk. Therapeutic risk is the risk or potential risks associated with an intervention that is required for medical care but occurs as part of the research. An example is an endoscopy that was required for medical follow-up of a specific illness. Research risk is associated with an intervention that is done for research purposes only regardless if it is an experimental intervention or a commonly used intervention, for example, an extra endoscopy.
Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

(Fill in answer to above question)

(2) Adequacy of Protection from Risks

(a) *Recruitment and Informed Consent*: Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document may not be submitted at this time.

(Fill in answer to above question)

(b) *Protection Against Risk*: Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve interventions, describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

(Fill in answer to above questions)

(3) Potential Benefit of the Proposed Research to the Subject and Others. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

(Fill in answer to above question)

(4) Importance of the Knowledge to be gained. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

(Fill in answer to above question)